## *Remarks*

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1 and 4-13 are pending in the application, with claim 1 being the independent claim. Claims 2 and 3 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

### *Summary of the Office Action*

In the Office Action dated July 18, 2002 (Paper No. 4), the Examiner objected to the priority disclosure, rejected claims 5, 6 and 9 under 35 U.S.C. § 112, rejected claims 1-13 under 35 U.S.C. § 102(b), and rejected claims 1, 2, 7, 8, 10 and 12 under 35 U.S.C. § 102(e). Applicants respectfully offer the following remarks, together with the above amendment, to overcome each of these rejections.

### *Regarding Priority*

In the Office Action, the Examiner objected to the priority disclosure on the ground that the status of the parent application should be updated. By the foregoing amendment, the priority disclosure has been amended to reflect the current status of the parent application.

Therefore, it is respectfully requested that the objection to the priority disclosure be withdrawn.

***Rejection under 35 U.S.C. § 112, first paragraph***

The Examiner rejected claims 5 and 6 under 35 U.S.C. § 112, first paragraph. More specifically, the Examiner contends the specification is not enabling for "biopolymers derived from heparin-tridodecylmethyl-ammonium chloride and other heparin complexes." Amended claims 5 and 6 recite heparin-tridodecylmethylammonium chloride and other heparin complexes, rather than biopolymers derived from these complexes. Since the Examiner stated the specification was enabling for biopolymers selected from heparin-tridodecylmethylammonium chloride and other heparin complexes, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 5 and 6 under 35 U.S.C. § 112, first paragraph.

***Rejections under 35 U.S.C. § 112, second paragraph***

The Examiner rejected claim 9 under 35 U.S.C. § 112, second paragraph, on the ground that claim 9 is indefinite because "there is a lack of antecedent basis for the term 'the heparin' since no such term has been previously set forth in any of claims 1, 7 or 9." Amended claim 9 recites "said biopolymer," which has proper antecedent basis in claims 1 and 7. In view of this amendment, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 9 under 35 U.S.C. § 112, second paragraph.

***Rejections under 35 U.S.C. § 102(b)***

In the Office Action at ¶¶ 7-11, the Examiner rejected claims 1-13 as being anticipated by Dyck (U.S. Patent No. 3,639,141), Nagata *et al.* (U.S. Patent No. 4,082,727), Morra *et al.* (WO 96/24392), Baney *et al.* (EP 0 581 576), and/or Rowland *et al.* (U.S. Patent No. 5,356,433). In view of the amendments herein, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-13 under 35 U.S.C. § 102(b).

***Rejection in View of Dyck, Morra et al., Baney et al., and Rowland et al.***

The Examiner rejected claim 1 as being anticipated by Dyck, Morra *et al.*, Baney *et al.* and/or Rowland *et al.* According to the Examiner:

> Dyck teaches that heparin (biopolymer) is bonded to the surface of a plastic in order to render the surface nonthrombogenic. In column 1, lines 28-35, Dyck teaches that heparin is bound to the surface of the plastic through an amino alkyl alkoxy silane. For claim 1, in column 2, lines 65-69, Dyck teaches that the amino groups of the silane readily bond with heparin. Thus the coating on the surface contains a biopolymer covalently bound to a silane.

Office Action at ¶ 7.

> For claim 1, on page 9, lines 9-14, Morra teaches a coating of hyaluronic acid for biomedical objects. On page 12, lines 24-34, Morra discloses that the hyaluronic acid is reacted with an alkoxy silane coupling agent. In the paragraph bridging pages 12 and 13, Morra teaches that a reaction product of hyaluronic acid and the silane formed, indicating the presence of a covalent bond. On page 1, lines 20-22, Morra describes that hyaluronic acid is a biopolymer in that it occurs naturally in practically all tissues.

Office Action at ¶ 9.

> For claims 1 and 7, on page 2, lines 1-3, Baney teaches the reaction of an organic polymer containing a hydroxyl group with an alkoxy silane. On page 4, line 3, Baney discloses that the polymer is a hydroxyl-functional polysaccharide. On page

> 5, lines 33-34, Baney teaches that the modified polymers may be used as protective coatings and biocompatible materials.

Office Action at ¶ 10.

> For claim 1, in column 5, lines 22-47, Rowland teaches that biologically active agents are covalently linked to an organosilane on a surface of a metal For claims 1 and 10, in column 5, lines 48-51, Rowland specifically mentions anti-thrombogenic agents such as heparin. Therefore, the coating contains a biopolymer that is covalently linked to a silane.

Office Action at ¶ 11.

Applicants have amended claim 1 to recite a Markush group of functional groups for the silane component of the composition. Claim 1 does not recite amino or alkoxy as a functional group. Thus, the covalent heparin-silane complexes of Dyck, Morra *et al.*, Baney *et al.* and Rowland *et al.*, do not have the same chemical structure as the product of the reaction between a biopolymer and a silane having the functional groups recited in claim 1. Therefore, the claimed coating compositions are not anticipated by Dyck, Morra *et al.*, Baney *et al.*, and Rowland *et al.* Since claims 4-13 depend on claim 1, they are patentable over Dyck, Morra *et al.*, Baney *et al.* and Rowland *et al.* for at least the same reasons discussed above for claim 1. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b).

***Rejection in View of Nagata et al.***

The Examiner rejected claims 1-13 under 35 U.S.C. § 102(b) as being anticipated by Nagata *et al.* According to the Examiner:

> For claim 1, in column 1, line 48 through column 2, line 7, Nagata teaches that an organosilicon compound (silane) is reacted with a heparin salt (biopolymer) to form an organosilicon compound with a heparin linkage, i.e. a

> covalent bond between the silane and the biopolymer (see also column 2, line 17). For claims 1 and 10 in column 5, lines 36-40, Nagata teaches that this material can be used as a coating, particularly for medical devices to impart an anticoagulant (thromboresistant) property to the medical device.

Office Action at ¶ 8.

Applicants have amended the transitional phrase in claim 1 from "comprising" to "consisting essentially of." Also, Applicants have amended claim 1 to recite that the covalently linked silane-heparin complex is capable of directly coating a surface of a substrate. These amendments are intended to clarify that the claimed coating composition does not require a primer or base layer in order to adhere to the surface of a substrate. Other additives may be added to the claimed composition as recited in dependent claim 12.

The claimed invention does not encompass a composition which includes an organosilicone resin bound to the silane-biopolymer complex as taught by Nagata *et al.* See Nagata *et al.* at column 3, line 56 through column 4, line 25. The claimed coating composition is capable of coating a substrate without a base or primer layer, and involves the silicon atom of the silane-biopolymer complex directly adhering to the substrate (see page 7, paragraph 33 of the specification). Therefore, the claimed coating compositions are novel and are not anticipated by Nagata *et al.*

Since claims 4-13 depend on claim 1, they are patentable over Nagata *et al.* for at least the same reasons discussed above for claim 1. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-13 under 35 U.S.C. § 102(b).

***Rejections under 35 U.S.C. § 102(e)***

The Examiner rejected claims 1, 2, 7, 8, 10, and 12 under 35 U.S.C. § 102(b) as being anticipated by Tsang *et al.* According to the Examiner

> For claim 1, in column 3, lines 50-55, Tsang teaches a coating composition that contains a silyl group covalently bonded to heparin. In column 5, lines 44-47, Tsang specifically teaches situations where n=1, indicating that a silane is present.

Office Action at ¶ 12.

Applicants have amended claim 1 to recite a Markush group of functional groups for the silane component of the composition. Claim 1 does not recite carbamate as a functional group. Thus, the covalent heparin-silane complexes of Tsang *et al.* do not have the same chemical structure as the product of the reaction between a biopolymer and a silane having the functional groups recited in claim 1. Therefore, the claimed heparin-silane compounds are not anticipated by Tsang *et al.*

Since claims 7, 8, 10 and 12 depend on claim 1, they are patentable over Tsang *et al.* for at least the same reasons discussed above for claim 1. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 7, 8, 10 and 12 under 35 U.S.C. § 102(e).

## *Conclusion*

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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## Version with markings to show changes made

***In the Specification:***

Please substitute the first pending paragraph on Page 1 of the Specification with the following paragraph:

This application claims the benefit under 35 U.S.C. § 120 as a divisional of U.S. Application [Serial] No. 09/138,464, filed August 21, 1998, now U.S. Patent No. 6,248,127 B1, herein incorporated by reference in its entirety.

***In the Claims:***

Please cancel claims 2 and 3 without prejudice or disclaimer.

Please substitute the following claim 1 for the currently pending claim 1:

1. (Once amended) A coating composition, consisting essentially of the product of the reaction of [comprising]:

a silane having at least one functional group selected from the group consisting of an isocyanate, an isothiocyanate, an ester, an anhydride, an acyl halide, an alkyl halide, an epoxide and an aziridine; and

a biopolymer, wherein said biopolymer is covalently linked to said [the] silane,[.]

and wherein said product is capable of directly coating a surface of a substrate.

Please substitute the following claim 4 for the currently pending claim 4:

4. (Once amended) The coating composition of claim 1, wherein said functional group is an isocyanate [the silane comprises isocyanate functionality].

Please substitute the following claim 5 for the currently pending claim 5:

5. (Once amended) The coating composition of claim 4, wherein [the] said biopolymer is [derived from] heparin-tridodecylmethylammonium chloride.

Please substitute the following claim 6 for the currently pending claim 6:

6. (Once amended) The coating composition of claim 1, wherein [the] said biopolymer is [derived from] a complex selected from the group consisting of heparin-tridodecylmethylammonium chloride, heparin-benzalkonium chloride, heparin-stearalkonium chloride, heparin-poly-N-vinyl-pyrolidone, heparin-lecithin, heparin-didodecyldimethylammonium bromide, heparin-pyridinium chloride, and heparin-synthetic glycolipid complex.

Please substitute the following claim 7 for the pending claim 7:

7. (Once amended) The coating composition of claim 1, wherein said [the] biopolymer has hydroxyl or amine functional groups [that can react with isocyanate functionality].

Please substitute the following claim 8 for the pending claim 8:

8. (Once amended) The coating composition of claim 1, wherein [the] said biopolymer comprises [an adduct of] heparin [molecules].

Please substitute the following claim 9 for the currently pending claim 9:

9. (Once amended) The coating composition of claim 7, wherein [the] said biopolymer [heparin] is provided in a form capable of dissolving in an organic solvent.

Please substitute the following claim 10 for the currently pending claim 10:

10. (Once amended) The coating composition of claim 1, wherein the biopolymer provides thromboresistance.

Please substitute the following claim 11 for the currently pending claim 11:

11. (Once mended) The coating composition of claim 1, wherein [the] said biopolymer is [derived from] heparin-tridodecylmethylammonium chloride.

Please substitute the following claim 12 for the currently pending claim 12:

12. (Once amended) The coating composition of claim 1, further comprising at least one additive selected from the group consisting of [a] wetting agents, surface active agents and film forming agents [agent and an additive].

Please substitute the following claim 13 for the currently pending claim 13:

13. (Once amended) The coating composition of claim 1, wherein the silane has an organic chain between isocyanate and silane functional groups.

**Applicants:** Shah *et al.*

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